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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,640	02/25/2002	Koichi Masuda	047940-0139	3691
23524	7590	12/20/2004	EXAMINER	
FOLEY & LARDNER 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/084,640	Applicant(s) MASUDA ET AL.	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/4/02</u> <i>to 10/12/03</i> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

In a response of 9/27/04 to a restriction requirement of 8/27/04, applicants elected Group I claims 1-8 and 14-19 with traverse.

The traverse requests that Groups I and II be examined together, and is on the ground that Groups I and II are closely related and searching both together will not be a serious burden on the examiner since a search of Group I will necessarily be coextensive with a search of Group II. However, as set forth in the restriction requirement, Group I claims are drawn to methods of producing intervertebral disc tissue or using such tissue to repair a disc damage, whereas the Group II claims are drawn to intervertebral disc tissue containing specific amounts of components such that the methods of the Group I claims can be performed without producing the tissue of the Group II claims. Thus, a search for the methods of the Group I Claims does not require a search for the specific tissue of the Group II claims, and the search for the Group I invention is not coextensive with a search for the Group II invention. Searching for the specific tissue of the Group II invention in addition to the methods of the Group I invention will be a serious burden on the examiner.

For the above reasons, the restriction requirement is still considered proper, and is adhered to and made final.

Claims 9-13 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely

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traversed the restriction (election) requirement in the reply filed on 9/27/04.

Claims 1-8 and 14-19 are examined on the merits.

On the last page of the pages of PTO-1449 filed 9/4/02, the penultimate document (Matsumoto et al (Ortho. Res. Soc. Trans.) has not been considered since a copy was not been received.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

12 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18 In line 5 of claim 1 and bridging lines 5 and 6 of claim 15, "cell-associated on" is uncertain as to meaning. It appears --- matrix --- should be inserted after "cell-associated" as in line 4 of claims 1 and 15.

24 Step (e) of claim 2 and step (v) of claim 16 are unclear by not having clear antecedent basis for removing engineered tissue from the membrane since tissue has not been previously required to be contained by the membrane. It is suggested that --- on the membrane --- be inserted after "tissue" in the last line of claims 1 and 15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- 6 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto et al (International Conference, Bone Morphogenetic Proteins 2000, June 7-11, 2000) (listed on form PTO-1449).

The claims are drawn to producing engineered intervertebral disc tissue by culturing intervertebral disc cells in a medium followed by culturing the cells on a semipermeable membrane in the presence of a growth factor. The medium can be an alginate medium. Also claimed, 18 is the resultant tissue, and a method of implanting tissue for repairing intervertebral disc damage.

Matsumoto et al disclose producing engineered intervertebral disc tissue for implanting to repair damaged intervertebral disc using a recently developed two step tissue engineering method referred to as the alginate-recovered-chondrocyte method, ARC method. The tissue is 24 produced using a culturing method that has the same steps and conditions as presently claimed, and tissue produced is the same as results from the presently claimed method. While Matsumoto et al does not disclose the composition of the medium during culture on the

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membrane, it appears that medium contains the growth factor, OP-1, as used in the medium prior to culturing on the membrane.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

6 (a) A patent may not be obtained though the invention is not identically disclosed
or described as set forth in section 102 of this title, if the differences between
the subject matter sought to be patented and the prior art are such that the
subject matter as a whole would have been obvious at the time the invention was
made to a person having ordinary skill in the art to which said subject matter
12 pertains. Patentability shall not be negated by the manner in which the
invention was made.

This application currently names joint inventors. In considering
patentability of the claims under 35 U.S.C. 103(a), the examiner
presumes that the subject matter of the various claims was commonly
owned at the time any inventions covered therein were made absent any
18 evidence to the contrary. Applicant is advised of the obligation
under 37 CFR 1.56 to point out the inventor and invention dates of
each claim that was not commonly owned at the time a later invention
was made in order for the examiner to consider the applicability of 35
U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art
under 35 U.S.C. 103(a).

24 Claims 1-18 and 14-19 are rejected under 35 U.S.C. 103(a) as
being unpatentable over Matsumoto et al in view of Masuda et al
(6,197,061 B1) or (6,451,060 B2).

The invention and Matsumoto et al are described above.

Masuda et al disclose a method having the same steps and
conditions as presently claimed except that chondrocytes are cultured

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to produce cartilage tissue. Masuda et al disclose a growth factor such as OP-1 present during culturing the cells on a membrane.

It would have been obvious to provide OP-1 in the medium used when culturing cells on the membrane in the method of Matsumoto et al as suggested by Masuda et al using the same culturing method to
6 produce tissue except for the type of tissue produced and having OP-1 present when culturing cells on the membrane, and as further suggested by Matsumoto et al disclosing that the method used is the alginate-recovered-chondrocyte method, which is the type of method disclosed by Masuda et al.

Claim Rejections - 35 USC § 103

12 Claims 1-8 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al (6,197,061 B1) or (6,451,060 B2) in view of Hanley Jr et al (6,080,579) or Matsumoto et al (applied above), and if necessary in further view of Chiba et al (Spine, Vol 23, 1998) or Chiba et al (Spine, Vol 22, 1997) (both listed on form PRO-1449).

18 The invention, Masuda et al and Matsumoto et al are described above.

Hanley Jr et al disclose producing intervertebral disc cells for implanting by growing chondrocytes in an alginate-containing medium (col 4, lines 1-36). The cells are recovered from the alginate and implanted directly or put on a bioresorbable carrier and implanted.

24 Chiba et al disclose growing intervertebral disc cells in an alginate medium.

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It would have been obvious to use the method of Masuda et al for producing intervertebral disc tissue for implanting as suggested by Hanley Jr et al using a similar method for growing intervertebral disc cells for implanting, or as suggested by Matsumoto et al using the same type of method for producing intervertebral disc tissue for
6 implanting. If needed, Chiba et al would have provided further disclosure of conditions for culturing intervertebral disc cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
12 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For
6 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

12 DMN
12/10/04